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PHOTOBIOMODULATION VERSUS CONSTRUCTED EXERCISE TRAINING PROGRAM IN COVID-19 SPONTANEOUSLY BREATHING PATIENTS ON HIGH FLOW OXYGEN

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ABSTRACT

The Corona virus has been a pandemic that grew the attention the medical field from all aspects. Controlling the spread and treating the infected has been the target focus of physiotherapy in ICU. The objectives of this study was to compare the effect of Photobiomodulation using Low level laser therapy to constructed exercise training program on COVID patients in the ICU. Over the course of 7 days 20 patients divided into 2 equal group, group "A" received treatment through medical interventions and Low Level Laser Therapy (LLLT) without constructed exercise training program and group "B" received medical interventions with Physiotherapy intervening without LLLT. Lab investigations to be compared were recorded on day 1 and day 7 including TLC, CRP, Ferritin, D-dimer, IL-6.

The obtained results regarding LLLT group, there were statistically significant differences in ferritin p = 0.005, D-dimer p =0.009, WBCs p = 0.005, and IL-6 p = 0.005. Regarding exercise group, there were statistically significant differences in IL-6 p = 0.005 and CRP p =0.004. Between-groups analysis showed that there was a statistically significant increase in WBCs in the LLLT compared to the exercise group p = 0.002. After seven days, LLLT affected ferritin, D-dimer, WBCs, and IL-6. Constructed exercise training program affected IL-6 p and CRP.

Key Words: COVID-19, Photobiomodulation, Low level laser therapy, exercise, ICU physical therapy.

INTRODUCTION

The World in 2019 - 2020 has faced one of the largest pandemics in the health systems in history (Corona virus) and the role of every bit and piece of the medical profession is paramount in defending against the further spread and worsening of such a virus.

The diversity of cases ranging from simple migraines and anosmia to the admission in the ICU and many times even the use of Mechanical Ventilators to support and prevent the demise of patients **(Karakuzu *et al.*, 2018)**.

However, the regression and progression of cases with the addition of physiotherapy in the ICU to improve muscle performance is important **(Severin *et al.*, 2020)**.

Respiratory physiotherapy interventions in hospital wards or ICU may be indicated for patients who have confirmed or suspected COVID-19 and concurrently or subsequently develop exudative consolidation, mucous hypersecretion and/or difficulty clearing secretions **(Thomas *et al.*, 2020)**.

Patients with a mild form of the disease should be instructed to perform breathing exercises independently. Early mobilization should be started as soon as possible, as long as the patient presents suitable clinical conditions **(Righetti *et al.*, 2020)**.

The purpose of this study was to investigate and compare the effect of Photobiomodulation and Constructed Exercise training program on patients with COVID-19 Spontaneously breathing on high flow oxygen in the ICU.

MATERIALS AND METHODS

1-Design and setting

Patients were recruited in this study from AlKasr AlAiny teaching hospitals ICUs in the Cairo district randomly divided into two equal groups. The study was conducted for 7 days in the ICU for each patient.

2-Procedures:

Ethical considerations

The protocol of this study was approved by the ethics committee of scientific research at the Faculty of physical therapy, Cairo University, Giza, Egypt. The study procedure was explained in detail to every patient before the initial assessment. All patients were informed about the purpose, nature, potential risks of the study, and written informed consent (Appendix I) was obtained before participation in the study. The participants' right to confidentiality was observed strictly.

Subjects

Twenty patients were recruited in this study representing both genders from AlKasr AlAiny teaching hospitals ICUs in the Cairo district aged from 35 to 55 years old. Patients recruited were diagnosed with COVID-19 and pleural effusion. Subjects were chosen for the study after meeting certain inclusion criteria. Inclusion criteria included patients aged from 35 to 55 years old. Patients diagnosed by CT or PCR as positive COVID-19. Patients with SPO2 on Room Air less than or equal to 75 - 85%. Moderate to severe cases of COVID-19 (According to CO-RADS Scale).

Patients excluded were On Invasive Mechanical Ventilation, Haemodynamically unstable with inotropic support, in septic Shock , admitted to the ICU in less than 24 hours, with a GCS less than 13/15 , feverish with other causes than chest infection, with an INR over 2.5. Added to this patients with severe electrolyte imbalance (K+ 2.5 or less resistant to correction. Na+ less than 115 with clinical manifestations.), Acute VTE without therapeutic anti-coagulation for over 48 hours, with Anuria without pathological Renal history, patients having emergency Cardiac Arrhythmias (V.F. or Pulseless V.T.) or having an unstable A.F. or Severe Tachycardia compared to baseline. Patients also excluded if Ongoing dialysis or blood transfusion or Refused Physiotherapy, or refusing life-saving medication referenced by the primary physician. Lastly in the exclusion criteria was the patient post-arrest less than 24 hours from time of session.

Randomization and allocation

Twenty patients were recruited in this study aged from 35 to 55 years old and randomly divided into two equal groups

1) Study group (A) included patients diagnosed with COVID-19 and pleural effusion who received medical interventions and Low-Level Laser Therapy (LLLT) without constructed exercise training program.

2) Study group (B) included patients diagnosed with COVID-19 and pleural effusion who received medical interventions with physiotherapy intervening without LLLT.

Clinical Assessment

Chest Computed Tomography, was done and patients were classified according to the CORADS from 1 to 5. Based on the CT findings, the level of suspicion of COVID-19 infection was graded from very low or CO-RADS 1 up to very high or CO-RADS 5 and the severity and stage of the disease was determined with remarks on comorbidity and a differential diagnosis. The interpretation of the CT findings was combined with the clinical symptoms and the duration of the symptoms as a CT can be negative in the first few days of a mild infection **(Bai *et al.*, 2020).** CT was recorded at the beginning and end of the study.

Pulse Oxymetry on Room Air less than or equal to 75 - 85 was excluded.

Modified Borg Scale Rate of Perceived Exertion (RPE) was explained to the patient according to the scale from 0 being no dyspnea to 10 being maximum shortness of breath and tire **(Boas *et al.*, 2013)** RPE was measured just after ankle pumps as a baseline and during exercise if the patient displayed symptoms and after the session.

ICU Monitor was used to record Vital signs, before, during, and after the session for any sudden changes.

Lab investigations; CBC, CRP, Ferritin, D-dimer and Interleukin-6 were recorded at the beginning and end of the study. SARS-CoV-2 infection induces a dose-dependent production of IL-6 from bronchial epithelial cells. ([Guideline] NIH. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. NIH, May 12, 2020). **Boschi *et al.,* (2008)** reported that LLLT (InGaAlP laser, 660 nm) significantly reduced the expression of IL-6 and TNF-α. LLLT has diverse effects including the reduction of IL-6. **(Scott *et al.*, 2020).**

Intervention:

For the study group (A):

Photobiomodulation Therapy

I) Laser: It is a safe noninvasive technology that utilizes visible light and infrared laser beams with the protocol for medium and severe COVID-19.

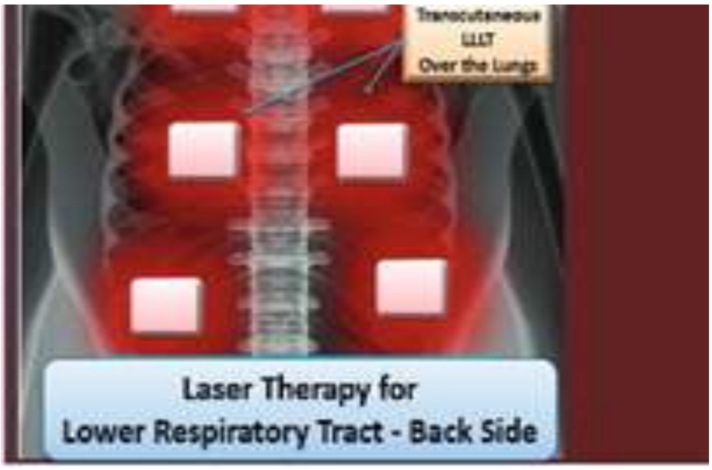
Low-level laser therapy (LLLT) can be added to the conventional treatment in COVID-19 at different stages of the disease. Because of its anti-inflammatory effect, and ability to shorten recovery times. LLLT can reduce the need of ventilators in the healing process.

Laser parameters:

- Laser type: Red laser (630–660 nm)
- Average power: 50–100 Mw
- Dose: 6–10 J/cm2• Area: 10 cm2 Total time by device per 10 cm2 is 6 minutes to deliver 90 J
- Time: 2–3 minutes/cm2
- Sessions: once-daily

Laser Shower Positions:

- Over the lungs: bilaterally over, middle, and lower lobes back of thorax and transcutaneous over the intercostal spaces **(Scott *et al.*, 2020).**



For the studied group (B) :

Constructed Exercise Therapy Training Program

I)Circulatory exercises: Active assisted or against mild resistance. Supine with Leg up position 18 degrees measured by the bed water balance in the side rails. If the patient was not comfortable according to the modified Borg scale or contra-indicated for the position, we would ask to assume the supine position.

The subjects had a 3-min rest period to acclimatize themselves to each position. The ankle pumping exercises consisted of simple repetitions of dorsiflexion for 1 sec and plantarflexion for 1 sec with three different exercise intervals:

- Repeated dorsiflexion and plantarflexion with no rest (no-rest exercise)
- Repeated dorsiflexion and plantarflexion with a 2-sec rest period (2-sec rest exercise)
- Repeated dorsiflexion and plantarflexion with a 4-sec rest period (4-sec rest exercise).

The subjects had practiced ankle pumps before the exercise to get familiar and be educated about the procedures, **(Toya *et al.*, 2016).**

II)Exercise training:

- Stretching exercises consisted of cervical, upper limb, and upper chest stretching. When stretching exercises were tolerated, the training session progressed to resisted activities **(Chen *et al.*, 2012)**.
- Turning from the one side to the other side when lying in the supine position and alternate supine bridging/buttock lift **(Mehrholz *et al.*, 2016).**
- Sit to Stand Training**, (Byul and Shin 2019**).

Exercise training on the basis of a Borg scale rating of 3–5.

Exercise paused or terminated when the subject presented the following intolerance signs and/or symptoms:

systolic blood pressure 200mm Hg, mean arterial blood pressure 65 mm Hg or 110 mm Hg; tachycardia or bradycardia; abnormal electrocardiogram waveform; respiratory rate40 breaths/min or 5 breaths/min; an oxygen saturation drop of 10%; or an overall oxygen saturation 88%.

III) Percussor. Using a frequency ranging from 20-30 cycles per second (CPS) for 3 minutes and over 40 watts as "in-phase vibration" (during inspiration) applied to improve dypsnea and heamodynamics:

- At the 2nd to 5th intercostal space parasternally.

- At the midaxillary line between the 7th to 9th intercostal space.

During gravity assisted positioning over the affected segments using the least frequency and during expiration.

V) Diaphragmatic release: Patient in the supine position. Stood on either side of the patient.

- Thumb tips placed inferolateral to the xiphoid process and the rest along the anterolateral costal margin below rib 7, which corresponded to muscular attachments of the respiratory diaphragm. The remaining digits rested along the inferolateral border of ribs 8-10.
- Patient was instructed to "take a deep breath and then breathe all the way out." As the patient exhaled, the diaphragm was followed by pressing thumbs posterior towards the bed.
- Held this point on the diaphragm as the patient took the next deep inhalation. During the next exhalation, a further cephalad motion of the diaphragm was recommended (within a reasonable means and not providing any excessive discomfort to the patient). Continued to monitor the superior movement of the diaphragm.
- Repeated steps for three to five respiratory cycles, or until the diaphragm domed easily at the end of exhalation.
- Re-assessment by monitoring the diaphragm for improvement in excursion.

VI) Incentive Spirometer (Plast-Med): The patient aimed to generate a predetermined flow or achieved a pre-set volume and was encouraged to hold at full inspiration for 2-3 seconds. The balls serve as visible feedback of the inspiratory flow. The patients were encouraged to use the device for 5–10 breaths per session, at a minimum, every hour while awake.

Data analysis: Data were obtained and statistically analyzed using SPSS for windows, version 25 (SPSS, Inc., Chicago, IL). The distribution of data was evaluated using the Shapiro-Wilk test. Normally distributed continuous variables were summarized by mean ± standard deviation (SD), while non-normally distributed continuous variables were expressed with median (interquartile range). Categorical variables were summarized by frequency and percentage. Independent and dependent t-tests were applied for normally distributed continuous variables. Mann–Whitney U-test and Wilcoxon signed-ranks test were performed for non-normally distributed continuous variables. Chi-square test was applied for nominal variables. The alpha level was set at 0.05.

Outcomes: Lab Investigations (Ferritin, D-Dimer, CRP, WBCs, and Interleukin-6) were assessed at baseline and post-intervention.

Data collection:

Data were screened, for normality assumption and homogeneity of variance. Normality test of data using Shapiro-wilk that revealed the data was normally distributed (P>0.05) after removal outliers that were detected by box and whiskers plots. Additionally, Levene's test for testing the homogeneity of variance revealed that there was no significant difference (P>0.05).

Statistical analysis

For each patient in the two groups, the data were gathered both before and after the treatment program. SPSS for Windows, version 18, was used to conduct the statistical analysis (SPSS, Inc., Chicago, IL). For subject characteristics, descriptive statistics in the form of mean and standard deviation were utilized. The tested variables of interest were compared for each patient before and after therapy using the T-test both within and between groups. P<0.05 was chosen as the threshold for statistical significance. The appropriate sample size for this study was 60 patients (30 individual per group).

RESULTS

Demographic characteristics of participants

As shown in Table (1) there were no significant differences between both groups in the demographic characteristics, including age and gender.

Table (1): Demographic characteristics of participants

Variable	**LLLT Group**	**Exercise Group**	**P Values**
	(n = 10)	**(n =10)**	
Age, y	**52.6 ± 2.95**	**50.9 ± 2.6**	**0.19§**
Gender (male), n (%)	**5 (50)**	**5 (50)**	**1¶**
Gender (female), n (%)	**5 (50)**	**5 (50)**	

Values are mean ± SD; §Values is an independent sample t-test; ¶ Value is a chi-square test; * Statistically significant.

Change in outcomes

Low-Level laser group

A Wilcoxon signed rank test revealed that there were statistically significant differences in ferritin scores p = 0.005, D-dimer scores p =0.009, WBCs scores p = 0.005, and Interleukin-6 scores p = 0.005 after the LLLT compared to before (Table 2).A paired-sample t-test revealed that there was no statistically significant difference in CRP after the LLLT compared to before p = 0.5(Table 3).

Exercise Group

A Wilcoxon signed rank test revealed that there was a statistically significant difference in Interleukin-6 scores after the exercise compared to before p = 0.005(Table 2). Additionally, A Paired-sample t-test revealed that there was a statistically significant difference in CRP after the exercise compared to before p = 0.004(Table 3). However, there were no statistically significant differences in ferritin scores p = 0.28, D-dimer scores p =0.09, and WBCs scores p = 0.8 after the exercise compared to before (Table 2).

Between-groups differences

Regarding change from baseline to post-intervention, a Mann–Whitney U test revealed that there was a statistically significant difference in WBCs in the LLLT compared to the exercise group = 0.002(Table 2). However, there were no statistically significant differences in Ferritin p = 0.08, D-dimer p = 0.16, Interleukin-6 p = 0.82, and CRP p = 0.82 in the LLLT compared to the exercise group (Table 2 and 3).

Table (2): Change in outcomes (non-parametric)

	LLLT Group (n = 10)	Exercise Group (n =10)	p-value§
1.Ferritin			
Baseline	1758 (1232-2096)	651 (357-1927)	0.07
Post-intervention	609 (426-1371)	751 (182-1468)	0.71
p-value¶	0.005*	0.28	
Change (Post - Pre)	/-755 (-1328--539)	/-257 (-1153-150)	0.08
2.D-dimer			
Baseline	1.9 (0.86-3.98)	1.5 (1.18-2.78)	0.88
Post-intervention	0.95 (0.78-1.65)	0.95 (0.85-2.3)	0.62
p-value¶	0.009*	0.09	
Change (Post - Pre)	/-1 (-2.33--0.21)	/-0.5 (-0.55-0.001)	0.16
3.WBCs			
Baseline	2950 (2278-4288)	2950 (2703-14765)	0.13
Post-intervention	8200 (6450-10450)	7700 (4450-12075)	0.71
p-value¶	0.005*	0.8	
Change (Post - Pre)	4600 (3175-6780)	465 (-5450-1875)	0.002*
4.Interleukin-6			
Baseline	150.5 (78.5-178.5)	136.5 (79.39-987.75)	0.45
Post-intervention	51 (23.5-81)	73.5 (38.275-265.75)	0.14
p-value¶	0.005*	0.005*	
Change (Post - Pre)	/-84 (-106.75--36)	/-72.71 (-199.25--26.5)	0.82

Values are Median (IQR); § Value is a Mann– Whitney U-test; ¶ Value is a Wilcoxon signed-rank test; * Statistically significant.

Table 3 Change in outcomes (Parametric)

	LLLT Group (n = 10)	Exercise Group (n =10)	p-value§	Mean Difference (95% CI)
1.CRP				
Baseline	40.76 ± 18.93	49.87 ± 30.7	0.43	-9.11 (-33.08 to 14.85)
Post-intervention	35.3 ± 11.52	27.82 ± 21.1	0.34	7.6 (-8.5 to 23.46)
p-value¶	0.5	0.004*		
Mean Difference (95% CI)	-5.46 (-23.21 to 12.29)	-22.05 (-35.30 to -8.8)		
Change (Post - Pre)	/-5.46 ± 24.82	/-22.05 ± 18.53	0.11	16.59 (-3.98 to 37.17)

°Values are mean ± SD; § Value is an independent sample t-test; ¶ Value is a dependent sample t-test; * Statistically significant.

DISCUSSION

This study was conducted to assess the effect of photobiomodulation and Constructed Exercise training program on patients with COVID-19 spontaneously breathing on high-flow oxygen in the ICU. The current study showed that, after seven days, LLLT affected ferritin, D-dimer, WBCs, and IL-6. Constructed exercise training program affected IL-6 p and CRP.

In the LLLT group, present findings showed that WBCs increased while ferritin, D-dimer, and IL-6 decreased. Regarding the photobiomodulation effects on COVID-19 patients, the results from current study are in agreement with other studies **(Scott *et al.*, 2020)** reported thatIL-6decreased from 45.89 to 11.7 pg/mL and ferritin from 359 to 175 ng/mL. Additionally, **(De Marchi *et al.*, 2021)** in an RCT, reported a statistical difference in favor of Photobiomodulation therapy in CRP. Moreover, **(Zwiri *et al.*, 2022)** showed that there was no statistical significance in the mean levels of IL-6 before and after treatment over time, not only that, but there was even an increase in the mean of IL-6 levels from baseline to post-treatment but clinically decreased only in the groups that received LLLT. This is clearly in concordance with the present study.

In the exercise group, the obtained findings showed that IL-6 and CRP decreased. Regarding the constructed exercise training program effects, the results in the IL-6 levels are in accordance with other studies**.** **Leandro *et al.*, (2020)**, demonstrated that regular, moderate exercise by older adults reduces concentrations of proinflammatory cytokines such as IL-6. Furthermore, **Magazanik *et al.*, (1988)** reported significant decrease in ferritin levels after a 7 day period of exercise. Other studies such as **(Ward *et al.*, 2020)** reported a decrease in ferritin levels after a training program **(Salgado *et al.*, 2021 and Gomide *et al.*, 2022)** reported that physical exercise had a significant effect in lowering CRP in COVID-19.

Concerning the WBCs, the positive effects shown in current study either with the photobiomodulation effects or the constructed exercise training program effects, are in concordance with several studies. **Sun *et al.*, (2021)**, explained that the severity and types of infections definitely play a role in the WBCs variations; in which patients are either able or unable to fight the infections. **Palladino, (2021)** also showed that WBCs are expected to rise when a patient is fighting and responding to the infection while patients in the ICU in the early days usually have the opposite effects with COVID-19. **Thomas *et al.*, (2020)** explained that this occurs in many conditions such as viral infections while the opposite in bacterial infections.

Regarding the D-dimer, the effects of Photobiomodulation therapy had a significant effect in being lowered which allows for a decreased incidence of coagulation. This is also shown in several studies which reveal the reduction effects of photobiomodulation on inflammatory markers such as the TNF and IL-6 which trigger the hypercoagulation process. **Soheilifar *et al.*, (2021)** explained that PBM is useful in decreasing TNFα levels.

As for the constructed exercise training program, present study showed no significant effects on the D-dimer levels which was also shown in other studies. **Koehler and Bottoni (2014)**, showed findings indicate that neither level of conditioning, nor short, intense exercise affected D-dimer levels.

D-dimer is a predictor and a re-evaluating factor to be considered in COVID-19 patients on admission and even out-patients. However, it should be pointed out clearly that D-dimer can be elevated by multiple conditions, either physiological such as old age or pathological such as rheumatoid arthritis. To sum up, having a high D-dimer does not diagnose a patient with COVID-19 rather it provides a good feedback if the patient is established to be COVID-19.

Interestingly, the results of current study concerning the effects of constructed exercise training program on IL-6 are not in accordance with other studies. **Donges *et al.*, (2010)**, showed that aerobic and resistance exercise in a group compared to a sedentary group didn't alter the IL-6. Furthermore, **Hojman *et al.*, (2019)** showed that exercise could increase IL-6 during lactate production during exercise.

Discussing the ferritin levels, **Skarpańska-Stejnborn *et al.*,(2015)** performed an exercise test that caused a significant increase in IL-6 and hepcidin levels, along with a 22 % increase in ferritin.

Studies that show increase in inflammatory cytokines such as IL-6 and ferritin are very limited but evident however in some studies. **Rico-Holgado *et al.*, (2021)** was one of few that opposed present study showing that low level laser therapy can induce IL-6 proliferation *In Vivo* and *In Vitro* .

To Further point out, **Feld *et al.*, (2020)** was in opposition with present study showing that out of 942 patients, the use of a lab investigation such as ferritin was a poor predictor of mortality.

Concerning the C-reactive protein, there are numerous studies that show statistical insignificance when adding low level laser therapy to the drug treatment but few that show even clinical insignificance. **Araujo *et al.*, (2013)** showed that C-reactive protein did not differ between groups. **Zwiri *et al.*, (2022)**, showed no statistical significance or clinical in CRP regarding low level laser therapy.

Burghardt *et al.*, (2019), concluded that there is no sufficient evidence that exercise reduces CRP levels or inflammatory markers. **Nazha and Bilen (2021)**, showed that an exercise training program had no effect on CRP, IL-6, or TNF-α serum level.

CONCLUSION

In COVID-19 spontaneously breathing patients on high flow oxygen in the ICU, LLLT affected ferritin, D-dimer, WBCs, and IL-6. Constructed exercise training program affected IL-6 p and CRP. Based on this study, COVID-19 patients can benefit from the use of Photbiomodulation therapy and constructed exercise training programs in reducing the inflammatory responses and improving infection markers.

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تضمين الاشعاع الضوئي مقابل برنامج تمارين مركب علي مرضي الكرونا الذين يتنفسون تلقائياً علي معدل تدفق اكسجين عال

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كان فيروس كورونا وباءً نما اهتمام المجال الطبي من جميع النواحي. كان التحكم في انتشار المرض وعلاجه هو الهدف الذي يركز عليه العلاج الطبيعي في وحدة العناية المركزة

مقارنة تأثير التعديل الحيوي الضوئي باستخدام العلاج بالليزر منخفض المستوى مع برنامج التدريب على التمرين المركب على مرضى COVID في وحدة العناية المركزة.

على مدار 7 أيام ، تلقى 20 مريضًا مقسمًا إلى مجموعتين متساويتين ، المجموعة "أ" تلقت العلاج من خلال التدخلات الطبية والعلاج بالليزر منخفض المستوى (LLLT) دون برنامج تدريبي مبني ، وتلقت المجموعة "ب" تدخلات طبية مع تدخل العلاج الطبيعي بدون LLLT. تم تسجيل التحقيقات المعملية المراد مقارنتها في اليوم الأول واليوم السابع بما في ذلك TLCو CRP و Ferritin و D-dimer و IL-6.

فيما يتعلق بمجموعة LLLT ، كانت هناك فروق ذات دلالة إحصائية في الفيريتين p = 0.005 ، D-dimer p = 0.009 ، WBCs p = 0.005 ، و IL-6 p = 0.005. فيما يتعلق بمجموعة التمرين ، كانت هناك فروق ذات دلالة إحصائية في IL-6 p = 0.005 و CRP p = 0.004. أظهر التحليل بين المجموعات أن هناك زيادة ذات دلالة إحصائية في كرات الدم البيضاء في LLLT مقارنة بمجموعة التمرين. p = 0.002

بعد سبعة أيام ، تأثرت LLLT بالفيريتين ، و D-dimer ، و WBCs ، و IL-6. أثر برنامج التدريب على التمرين المركب على IL-6 p و CRP.